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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
ART UNIT	PAPER NUMBER
	7

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Application No.	Applicant(s)
09/552,087	BYRUM ET AL
Examiner	**Art Unit**
Juliet C Einsmann	1655

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *4,8 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7,9 and 10* is/are rejected.

7)☒ Claim(s) *1-3,5-7,9 and 10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 5-7, 9-10, drawn to nucleic acids, host cells, and transgenic plants, wherein the expression constructs comprise the nucleic acid in the sense orientation, classified in class 536, subclass 23.1, for example.

II. Claim1-10, drawn to nucleic acids, host cells, and transgenic plants, wherein the expression constructs comprise the nucleic acid in the anti-sense orientation, classified in class 536, subclass 24.5, for example.

III. Claim 11, drawn to method for determining a genomic polymorphism in a plant that is predictive of a trait, classified in class 435, subclass 6.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. Applicants must further elect a single nucleic acid sequence for examination.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are drawn to distinct products. The effects of transforming a host cell or transgenic plant with a sense versus anti-sense molecule are different and unpredictable from one another. Claims 1-2, drawn to nucleic acids were included with both groups and will be examined with the elected group.

3. Inventions I and III and inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention I and II are useful in other methods such as methods for transforming plants, nucleic purification methods, and aptamer methods.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-III require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Lawrence Lavin on 7/16/01 a provisional election was made with traverse to prosecute the invention of group I, claims 1-3, 5-7, and 9-10. Applicant further elected SEQ ID NO: 1 for prosecution. Affirmation of this election must be made by applicant in replying to this Office action. Claim 4, 8, and 11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

7. Claims 1-3, 5-7, 9, and 10 are objected to for containing non-elected subject matter. Amendment of the claims to reflect the election of SEQ ID NO: 1 is required.

Sequence Rules

8. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s):

Pages 96-97 recite sequences which are not properly identified with sequence identifiers.

In order to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), Applicant must submit an amendment directing the insertion of the SEQ ID NOs into the appropriate pages of the specification. Furthermore, as appropriate, applicant must submit a new CRF and paper copy of the Sequence Listing containing these sequences, in addition to the previously listed sequences, an amendment directing the entry of the Sequence Listing into the specification, and a letter stating that the content of the paper and computer readable copies are the same.

Specification

9. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or

other form of browser-executable code, for example on pages 1, 4, 5, 7, 24, and 96. See MPEP § 608.01.

Claim Rejections - 35 USC § 112 2nd paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-2 and 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) Claims 1-2 are indefinite over the recitation of "capable of hybridizing" because capability is a latent characteristic and the claims do not set forth the criteria by which to determine capability. That is, it is not clear whether the recited probes have the potential to hybridize or do in fact hybridize to SEQ ID NO: 1. Amendment of the claim to read, for example, "which hybridizes" would obviate this rejection.

(B) Claims 5 and 6 recite the limitation "the transformed plant according to claim 3" in line 1. There is insufficient antecedent basis for this limitation in the claim because claim 3 does not recite a transformed plant.

Claim Rejections - 35 USC § 101

12. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

Claims 1-3, 5-7, and 9-10 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use.

The elected claims are drawn to nucleic acids capable of hybridizing to SEQ ID NO: 1, as well as host cells and transgenic plants comprising these nucleic acids.

A well-established utility is defined as a specific, substantial and credible utility which is well known, immediately apparent or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. The instant nucleic acids do not have a well established utility because the art does not teach any utility for the instantly claimed nucleic acids that is specific, substantial, and credible.

The specification discloses a number of general utilities for such nucleic acids. For example, the specification generally discloses that these nucleic acids are useful in genetic mapping studies (p. 35), physical mapping (p. 43), contig mapping (p. 46), comparative mapping (p. 49-56), the identification of polymorphisms (p. 49-56), monitoring expression (p. 56),

locating regions of identity by descent between individuals (p. 58), isolating clones (p. 59), microarray based methods (p. 60), direct site mutagenesis (p. 60), transformation (p. 62-80), in cosuppression (p. 80), to reduce gene function (p. 82), and as antibodies (p. 83). None of these asserted utilities are specific because the disclosed uses of the nucleic acids are generally applicable to any nucleic acid and therefore are not particular to the nucleic acid sequences being claimed. No specific function of the polypeptide encoded by SEQ ID NO: 1 has been provided, nor has it been demonstrated that SEQ ID NO: 1 has any utility as a marker for a specific phenotypic trait. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities, and this is particularly the case with regard to correlation with phenotypic traits or genetic mapping of phenotypic traits. Further, the use of the instantly disclosed polynucleotides to produce the protein encoded by the nucleic acid is not a specific or substantial utility since there is no known utility for the polypeptide. No utility has been described for the transgenic plants comprising these nucleic acids. The specification has provided not information as to what effect the expression of SEQ ID NO: 1 in a transgenic plant would have on the plant. After further research, a specific and substantial credible utility might be found for the claimed nucleic acids. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's invention is incomplete.

As noted by Brenner v. Manson, 383 U.S. 519, 535-536 (1996), "Congress intended that no patents be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing...a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Neither the specification as filed nor any art of

record discloses or suggests any property or activity for the claimed nucleic acids such that another non-asserted utility would be well established for the compounds.

For these reasons, the claimed polynucleotides, host cells and transgenic plants are not supported by either a specific and substantial asserted utility or a well established utility. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed.

Claim Rejections - 35 USC § 112, 1st paragraph

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-7, 9, and 10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

For all the above reasons, the disclosure is insufficient to teach one of skill in the art how to use the invention. A review of *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) clearly points out the factors to be considered in determining whether a disclosure would require undue experimentation and include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these

factors are considerations when determining the whether undue experimentation would be required to use the claimed invention. As is evidence in the discussions *supra*, each of these factors has been carefully considered in the instant grounds of rejection, and it is maintained that undue experimentation would be required by the skilled artisan to use the instant invention.

14. Claims 1-5, 7, and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The elected claims are drawn to nucleic acids capable of hybridizing to SEQ ID NO: 1, as well as host cells and transgenic plants ***comprising*** these nucleic acids. The instant specification describes a nucleic acid consisting of SEQ ID NO: 1. These claims encompass a large genus which includes the full length coding sequence of which SEQ ID NO: 1 is a fragment, the full length gene of which SEQ ID NO: 1 may be a part, genes which are similar to SEQ ID NO: 1 from other organisms, as well as any variants of SEQ ID NO: 1 which have been modified by any insertion, deletion, addition or subtraction. Claim 2 is specifically drawn to nucleic acid molecules which comprise regions having single nucleotide polymorphisms, yet the specification has not provided any SNP's in SEQ ID NO: 1. Claims 3, 5-7, and 9-10 are further drawn to comprise constructs which comprise only a fragment of SEQ ID NO: 1. However, the specification has provided no guidance or description as to how to select fragments from SEQ ID NO: 1 which will retain the function of SEQ ID NO: 1.

With regard to the written description, all of these claims encompass nucleic acid sequences different from those in the SEQ ID No. 1 for which no written description is provided in the specification.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. Concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only SEQ ID NO: 1 is described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception or written description of any nucleic acid other than those disclosed.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Marek *et al.* (GenBank Accession AQ989165, March 2000).

Marek *et al.* teach a nucleic acid which is capable of specifically hybridizing to a nucleic acid molecule having SEQ ID NO: 1. Nucleotides 5-344 of the sequence taught by Marek *et al.* have 97.4% sequence identity with nucleotides 4-343 of SEQ ID NO: 1. Furthermore, Marek *et*

al. teach that this sequence is from a library with 40,000 clones. These clones represent host cells which comprise a fragment SEQ ID NO: 1, since the sequence taught by Marek *et al.* has 100% identity with a number of stretches of SEQ ID NO: 1. Thus, the teachings of Marek *et al.* meet the limitations of claims 1-3.

16. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Wing *et al.* (GenBank Accession AQ256798, October 1998).

Wing *et al.* teach a nucleic acid which is capable of specifically hybridizing to a nucleic acid molecule having SEQ ID NO: 1. Nucleotides 219-468 of the sequence taught by Wing *et al.* have 64% sequence identity with the complement of nucleotides 85-334of SEQ ID NO: 1. Furthermore, Wing *et al.* teach that this sequence is a clone from a Rice BAC library. This clone is a host cell which comprises a fragment SEQ ID NO: 1, since the sequence taught by Wing *et al.* has 100% identity with a number of stretches of SEQ ID NO: 1. Thus, the teachings of Wing *et al.* meet the limitations of claims 1-3.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 16 of copending Application No. 09/421106. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '106 application are drawn to nucleic acids which hybridize under specifically recited conditions to SEQ ID NO: 5 as described in the '106 application. SEQ ID NO: 5 in the '106 application is identical to SEQ ID NO: 1 in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1-3, 5-7, and 9-10 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 09/521640. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-15 of the '640 application are drawn to include nucleic acids, vectors, host cells, and transgenic plants which hybridize to or comprise SEQ ID NO: 141338. SEQ ID NO: 141338 in the '640 application is identical to instant SEQ ID NO: 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

21. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA § 102(e)).

Claims 1-3, 5-7, and 9-10 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/421106 or 09/521640 which have a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the copending applications, each would constitute prior art under 35 U.S.C. 102(e), if patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future patenting of the copending application. Each of these applicantions disclose nucleic acids, vectors, host cells, and transgenic plants which comprise instant SEQ ID NO: 1. In the '106 application, SEQ ID NO: 5 is identical to instant SEQ ID NO: 1. In the '640 application, SEQ ID NO: 141,338 is identical to instant SEQ ID NO: 1.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

22. Claims 1-3, 5-7, 9, and 10 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

In light of the previously filed co-pending applications 09/421106 and 09/521640 which both disclose the instantly claimed invention and whose inventive entities both differ from the instant application it appears that the inventive entity in the instant application did not invent the claimed subject matter.

Conclusion

23. No claims are allowed.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C. Einsmann
Examiner
Art Unit 1655

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

September 13, 2001